

## REMARKS

In accordance with the above amendments, claims 10, 11, 18 and 24 have been amended and claims 10-24 remain under consideration in this application. No claim has been allowed.

### **Comments Regarding Applicant's Invention:**

With regard to applicant's invention, certain additional explanatory remarks are believed to be in order. With regard to the embodiments encompassed by amended claims 10-17, the system for reducing potential for substance abuse in skin-worn patch devices requires a separate disposable container which clearly is neither secured to nor part of the skin-worn patch device itself. A layer in the separate container includes the anti-abuse substance which is effective when a patch is inserted into the container in the proper orientation such that the abusable substance and the anti-abuse substance layers face each other and come into contact. The container into which the skin-worn patch device is inserted in a separate article that forms no part of the patch device itself, and no anti-abuse substance is contained in the skin-worn patch itself.

The embodiments encompassed by claims 18-24 include a skin-worn transdermal patch having a dual-layer system in which an anti-abuse layer and the abusable or therapeutic substance layer are both contained in the patch, but are separated by an impermeable membrane which remains in place during normal use of

the patch. It is only at the time that the patch is removed from the skin of a user, and by the act of removal, that the separator membrane is caused to be withdrawn from between the anti-abuse layer and the abusable substance layer. Abuse prevention thus thereafter happens automatically. This technique is decidedly associated with removal of a used patch.

#### **Claim Rejections - 35 USC § 103**

Claims 10, 11, 15-19, 23 and 24 have been rejected under 35 USC § 103(a) as being unpatentable over Sackler (US Publication 2003/0068392 A1) in view of Stanley et al (USPN 6,261,595 B1). This rejection is respectfully traversed.

The primary reference, Sackler '392, does disclose transdermal delivery systems in which an abusable subject, such as opioid, is combined with an antagonist for the opioid in a transdermal delivery system. In one embodiment, the opioid agonist and an adverse agent can be separated by a layer which becomes disrupted when the dosage form is tampered with, thereby mixing the aversive agent with the opioid agonist. Sackler '392, however, fails to teach or suggest any of the claimed anti-abuse arrangements of the present invention. Thus, Sackler fails to teach a separate disposal container for the anti-abuse substance which is not part of the skin-worn patch, and Sackler fails to teach an impermeable separation membrane which is automatically removed upon removal of the patch from a user's skin thereby

preventing tampering with a used patch.

The secondary reference, Stanley et al. '595, discloses a patch with a heating element pouch as an integral part of the patch. That pouch is substantially filled by the heating element for use with that patch device. The pouch of Stanley is not a separate and distinct entity from the patch device as required in independent claim 10 nor does it contain any anti-abuse substance as is required in applicants' claim 10. Claims 11 and 15-17 depend from and further limit claim 10.

While Sackler '392 does include an antagonist in the patch, it is not separated by a membrane linked to a removal device activated by removal of the patch as is required by claim 18 and claims 19 and 23-24 that depend from and further limit claim 18.

Thus, it is clear that the independent claims of the present invention distinguish over any combination of Sackler and Stanley et al. Since all other claims add additional limitations, they also distinguish. The combination neither teaches nor suggests devices covered by any of the present claims. Reconsideration and withdrawal of this rejection is respectfully requested.

Claims 10, 11, 15-19, 23 and 24 have also been rejected under 35 USC § 103(a) as being unpatentable over Sackler '392 or Gale et al. (USPN 4,588,580) in view of Stanley et al. '596 and Lee et al. (USPN 5,236,714). This rejection is also respectfully traversed.

Sackler '392 and Stanley '596 have clearly already been distinguished. Gale et al. '580 describes a transdermal delivery system for delivery of fentanyl and its derivatives which shows, in one embodiment, a patch with an integral pouch. This reference is also believed irrelevant to the concept of a separate container for disposing of a skin-worn patch, which container contains the anti-abuse substance, as Gale discloses neither a separate container nor an anti-abuse substance and whether or not the rate controlling membrane 3 could serve as a closure means is of no consequence given the fundamental differences in the present claims.

Lee et al. '714 discloses a dosage form in which an abusable substance is mixed with an antagonist in the same reservoir. The anti-abuse systems and techniques disclosed in that reference are not seen to be relevant to any of the techniques or embodiments of the presently claimed invention.

In view of the above, it is believed that no combination of the patents applied in the present rejection would result in anything that either teaches or suggests the present claims. Accordingly, reconsideration and withdrawal of this rejection is respectfully requested.

The Examiner's comments regarding the obviousness of one skilled in the art providing the separate pouch to dispose of the drug delivery system of Sackler or Gale or Lee has no basis in

the prior art. Not only do the present claims require or are directed to those embodiments require a separate pouch, the pouch must contain the anti-abuse substance and the disposed patch must be placed and contained in a proper orientation. None of this is suggested or taught by any of the prior art cited. Clearly, no motivation exists for such a device as, for example, the patch as disclosed by Sackler and Lee contain their own antagonist within the patch.

Finally, claims 12-14 and 20-23 have been rejected under 35 USC § 103(a) as being unpatentable over Sackler '392 or Gale '580 or Lee '714 in view of Schoendorfer et al. (USPN 5,899,856). This rejection is respectfully traversed.

Sackler, Gale and Lee have already been more adequately distinguished from any of the claims in the present application and the addition of any charcoal-containing binding or absorption pad as may be taught in Schoendorfer et al. '856 has no bearing on the clear basic differences between the presently claimed invention and the other three references. Also, if one was to mix an activated carbon with the transdermal patch during formulation as suggested by the Examiner, no drug would be delivered at all as it would then immediately become bound to the charcoal. The Schoendorfer et al. carbon patches are also used for entirely different purposes and the anti-abuse device configuration claimed is neither taught nor suggested.

Reconsideration and withdrawal of this rejection is respectfully requested.

The other references cited by the Examiner have been carefully considered and the claims are believed to be clearly patentable over any of these.

In view of the above amendments taken together with the remarks herein the Examiner is respectfully requested to reconsider his position, withdraw the rejections and allow all of the claims.

Respectfully submitted,

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A handwritten signature in cursive script, appearing to read "C. G. Mersereau".

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